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FIVE-DAY DOSING OF SYNTHETIC EXENDIN-4 (AC2993) IN PEOPLE WITH TYPE 2 DIABETES REDUCES POST-PRANDIAL GLUCOSE, GLUCAGON AND TRIGLYCERIDE CONCENTRATIONS

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Background and Aim: We evaluated the safety, tolerability, and efficacy of synthetic exendin-4 (AC2993) in 24 patients with type 2 diabetes (DM2) previously treated with diet, oral hypoglycemic agents (OHA), or insulin in a single-blind, placebo controlled, two-period crossover study.

Materials and Methods: 14 days prior to randomization, OHA therapy was stopped and subjects using insulin were stabilized on a single is NPH injection. Each patient was randomized to receive subcutaneous (SC) injections BID (7:00 and 17:00 hrs) of placebo (PBO) or 0.1 µg/kg AC2993 for 5 days. Following a 2-3 day washout, subjects were crossed over to the other treatment. Plasma glucose (PG), glucagon and serum triglyceride (TG) concentrations were assessed fasting and in response to a 7 Kcal/kg Sustacal® meal administered at the time of the morning AC2993/PBO injection on days 1 and 5.

Results: Reported adverse events, ECG, physical exam, and safety lab monitoring revealed no safety issues. Nausea and vomiting were the most frequent adverse events; however all were reported as mild in intensity. Postprandial circulating PG, glucagon, and TGs were significantly reduced following AC2993 compared to PBO on both days 1 and 5. On day 5, the 3-hour time-weighted mean \pm SE change in PG from baseline fasting values was -7.7 ± 5.1 mg/dL for AC2993 compared to 67.2 ± 7.9 mg/dL for PBO, ($P < 0.0001$). The 3-hr postprandial plasma glucagon AUC was reduced by 23% compared to PBO ($P = 0.0123$) and the rise in postprandial TGs was suppressed as evidenced by a 24% reduction in peak postprandial TG concentrations compared to PBO ($P = 0.0001$).

Conclusions: 0.1 µg/kg AC2993 BID for 5 days in patients spanning the spectrum of type 2 diabetes identified no safety issues, reduced circulating postprandial plasma glucose, glucagon and triglyceride concentrations.

Clinical diabetes